FDA News

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Food and Drug Administration Seeks Injunction Against Pacific Shellfish, Inc.

The U.S. Food and Drug Administration (FDA) is seeking a permanent injunction against Pacific Shellfish, Inc., a seafood processor located at 5040 Cass Street in San Diego California, and Judd J. Brown, its President. An injunction is a court order to stop a firm from manufacturing, distributing, processing, or shipping a product. The government's complaint, filed on January 24, 2006 by the U.S. Department of Justice in the U.S. District Court for the Southern District of California, charges the defendants with violating the Federal Food, Drug, and Cosmetic Act by permitting ready-to-eat fish held and processed in Pacific Shellfish's facility to become contaminated.

According to the complaint, recent FDA inspections in 2004 and 2005 revealed the presence of *Listeria monocytogenes* (*Listeria*), a disease-causing bacterium, on Pacific Shellfish's processing equipment and fish products. Inspections since 2001 have also documented persistent insanitary conditions at the facility. FDA issued a letter to the firm on December 8, 2004, after an inspection revealed insanitary conditions and contamination with *Listeria*. Although the firm promised to correct its deficiencies, a 2005 inspection found that a persistent strain of *Listeria* remained and the firm had not implemented all of the promised corrections.

Listeria monocytogenesis the causal agent of listeriosis, a disease that can be very serious, even fatal, for high-risk groups such as pregnant women, unborn babies, newborns, and those with impaired immune systems. Although proper cooking can eliminate Listeria in fish products, raw fish products, such as those found in some types of sushi, pose a serious health risk if contaminated with Listeria. Even if fish is intended to be cooked, however, adequate sanitation is needed to prevent the spread of this strain of Listeria throughout the distribution system to restaurants and consumer homes, where it may contaminate ready-to-eat foods. The Listeria monocytogenes strain isolated from the 2004 and 2005 inspections was identical to a strain that has caused human illness.

The FDA has initiated this action to promote and protect the public health by enforcing the Federal Food, Drug, and Cosmetic Act. FDA's mission includes ensuring the safety or safety and effectiveness of a broad spectrum of regulated products, including food, human and animal drugs, vaccines, blood products, medical devices, electronic products that emit radiation, and cosmetics.